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EXAMINER
MARSCHEL, A

ART UNIT 187 | PAPER NUMBER 3

DATE MAILED: 01/29/90

[illegible] of this communication to your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☒ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-17 are pending in the application.
   Of the above, claims 9-17 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-8 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-17 are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180, Art Unit 187.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to methods of detection using PCR amplification, classified in Class 435, subclass 6.

II. Claims 9-17, drawn to DNA sequences for the gene coding for dystrophin, classified in Class 536, subclass 27.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as a substrate in sequencing reactions to determine the sequence of the surrounding gene region of the said product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Thomas Paul on 1/4/90 a provisional election was made with traverse to

prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in responding to this office action. Claims 9-17 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the use of primers for which the DNA sequences are known. The practice of this invention is only enabled over known sequences. For example, claim 2 implies that the entire X or Y chromosome is available for this technique. It would take undue experimentation to determine sequence sufficient to cover either one of these chromosome completely. See MPEP 706.03(n) and 706.03(z).

The following is a quotation of 35 U.S.C. 103 which

forms the basis for all obviousness rejections set forth in this office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-8 are rejected under 35 U.S.C. 103 as being unpatentable over Kogan et al.

The instant application is directed to the PCR amplification of target DNA sequences where a plurality of primer pairs are used simultaneously for the amplication of multiple sequences. This technique is also directed to the detection of specific diseases.

Kogan et al. discloses the PCR reaction to diagnose a variety of genetic diseases as summarized in the abstract, last 6 lines. Sex-linked disorders are examined as exemplified by the use of sequences specific for the Y chromosome. See Figure 3 on page 989. The

simultaneous amplification of multiple sequences is disclosed on page 990, first column, lines 24-27. The motivation to examine multipe disorders is given in the last paragraph of the abstract by the examples of the wide variety of possible mutations linked to genetic disorders that can be investigated using the disclosed method.

In summary, the disclosure of Kogan et al. gives the motivation and technique to apply PCR to amplify target sequeneces simultaneously. Thus, someone of ordinary skill in the art at the time of the instant application would have obviously used the PCR technique to detect mutations as is given in the prior art.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

> (a) the invention was known to used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Kogan et al.

As summarized above Kogan et al. discloses the use of the PCR technique to a variety of disorders, especially of the X and Y chromosome. The disclosure of the use of simultaneous multiple primer pairs for the detection of these disorders reads on claims 1-5 of the instant application.

Any inquiry concerning this communication should be directed to Ardin Marschel, Ph.D., at telephone number: 703-557-0664

AM

A. MARSCHEL:am

Jan. 12, 1990

Amelia B. Yarbrough

AMELIA BURGESS YARBROUGH
PRIMARY EXAMINER
ART UNIT 183